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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LELA KING, Plaintiff, vs. ETHICON, INC., and JOHNSON & JOHNSON. Defendants.	CASE NO.: 3:21-cv-17983

FIRST AMENDED COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff LELA KING files this First Amended Complaint and for causes of action against Defendants ETHICON, INC., and JOHNSON & JOHNSON ("Ethicon Defendants") and alleges as follows:

JURISDICTION AND VENUE

1. This Court has personal jurisdiction over all Defendants as they are incorporated in in New Jersey and/or maintain their principal and regular place of business in New Jersey and through their substantial and purposeful transactions of business in New Jersey. Plaintiff was implanted with Defendants' synthetic mesh product that was designed, manufactured and sold in

interstate commerce (including New Jersey and North Carolina). Defendants have significant contacts with New Jersey such that they are subject to personal jurisdiction within this District.

2. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because it is a civil action in which the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between citizens of different States.

PARTIES

3. Plaintiff LELA KING ("Plaintiff") is, and was at all relevant times, a resident of North Carolina.

4. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson with its corporate headquarters in Somerville, New Jersey. Defendant Ethicon is a foreign corporation licensed to do business in the State of New York and may be served with process by serving its registered agent, Office of the New York Department of State, One Commerce Plaza, 99 Washington Avenue, Albany, NY 12231. Defendant Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson.

5. Defendant Johnson & Johnson (sometimes referred to herein as "J&J") is a New Jersey corporation that has its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey. Defendant Johnson & Johnson does business in the State of New York and may be served with process by serving its registered agent, Office of the New York Department of State, One Commerce Plaza, 99 Washington Avenue, Albany, NY 12231.

6. According to its website, Johnson & Johnson is the world's largest and most diverse medical and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J organizes its subsidiary businesses

into individual Business Units to coordinate the development, manufacture, testing, marketing, promotion, training, distribution, and sale of its' pelvic floor repair products, including the product at issue herein. Within J&J there are three business segments, medical devices, pharmaceutical, and consumer. Within the medical devices segment are "Business Units," including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution, and sale of the product at issue in this case. The Chairman for the Ethicon Franchise is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled and managed by J&J and include, but are not limited to Ethicon, Inc.

7. J&J has direct or constructive possession or control of Ethicon's assets and decision-making. Acting through its business units which make up its Medical Devices business segment, including Ethicon, Inc., J&J was involved in the continued research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of medical devices including the TVT device at issue in this case.

8. J&J is a holding company, the purpose of which is (1) to coordinate the administration, finances, and activities of its subsidiary companies and business units including Ethicon, Inc.; (2) to act as manager; and (3) to direct or coordinate the management of its subsidiary companies and business unites or of the business, property, and estates of any subsidiary company and business units, including Ethicon, Inc.

9. The website on which the pelvic repair mesh products are or were listed, described, and marketed, including the product at issue in this case, has at all times been maintained and operated by J&J. See https://www.jnjmedicaldevices.com/en-US/companies/ethicon (last viewed 7/16/2020).

10. The financial accounts of the Ethicon, Inc. business unit are consolidated within those of J&J. Ethicon's assets and properties are controlled by J&J.

11. J&J is the owner of 100% of the shares of Ethicon, Inc. stock and assets, including the rights to Ethicon, Inc.'s patents and intellectual property. J&J has control over Ethicon Inc.'s activities, operations, and policies.

12. Ethicon, Inc. acts solely as agent for J&J and Ethicon, Inc.'s policies and business operations and decisions have been controlled by J&J. J&J and Ethicon combine their property and labor in a joint venture, enterprise, or undertaking for profit, with rights of mutual control.

13. J&J is liable for any acts and/or omissions by or through Ethicon, Inc. Ethicon, Inc. is organized and controlled, and its business is conducted in such a manner as to make it merely an agent, alter ego, or business conduit of J&J. J&J has not dealt with Ethicon, Inc. at arms-length but instead has dominated and controlled Ethicon, Inc.'s activities, policies, and decisions. For example, J&J has made the decision to restructure the Medical devices business segment to which the Ethicon business unit belongs as a streamlining and cost-savings measure. J&J's restructuring of the Medical Devices business segment resulted in a decrease or discontinuation of investment and research and development with respect to pelvic mesh and other surgical mesh devices and elimination of a sizeable portion of the workforce within the Medical Devices business segment, including many at Ethicon, Inc.

14. J&J has mingled the accounts, records, and property of Ethicon with its own. J&J has held itself out to the public as one entity with business unit/division Ethicon, Inc. J&J has expressly or impliedly assumed Ethicon's liabilities, including liabilities associated with the pelvic mesh product implanted in Plaintiff. J&J insures Ethicon, Inc. and its other business units against product liability claims through a wholly owned, captive insurance company. J&J has

paid Ethicon, Inc.'s debts and expenses. Because Ethicon, Inc.'s assets and capital are subject to the ownership and control of J&J, and because the corporate form of Ethicon, Inc. has been disregarded and abused by J&J, Ethicon, Inc. is undercapitalized and the failure to disregard Ethicon, Inc.'s corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Ethicon, Inc. By assuming Ethicon, Inc.'s liabilities, disregarding Ethicon, Inc's corporate form, and by taking affirmative actions to deplete the assets of Ethicon, J&J has promoted a fraud or injustice on Plaintiff.

15. J&J, directly and/or through the actions of its agent and business Ethicon, Inc., has at all pertinent times been responsible for the research, design, development, testing, manufacture, production, marketing, promotion, labeling, distribution, and/or sale of the TVT product at issue in this civil action.

16. Defendants are individually, jointly, and severally liable to Plaintiffs for damages suffered by Plaintiff arising from the Defendants' design, manufacture marketing, labeling, distribution, and sale if their TVT product at issue in the instant suit, effectuated directly and indirectly though their respective agents, servants, employees, and/or owners, all acting within the course and scope of their respective agencies, services, employments, and/or ownership.

17. To the extent that Ethicon is claimed to maintain any separate corporate identify from J&J, the corporate identify of Ethicon should be pierced so that Ethicon's assets and liabilities are considered the assets and liabilities of J&J, and J&J should be held liable in the same manner as Ethicon, Inc. for any and all of Plaintiff's injuries and damages.

18. Defendants are vicariously liable for the acts and omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

19. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and /or selling such devices, including the TVT. Defendants manufacture, market, advertise, promote, and sell products worldwide.

20. Johnson & Johnson and Ethicon Inc. are collectively referred to herein as "Defendants," "Ethicon Defendants," or "Ethicon."

FACTUAL BACKGROUND

The Pelvic Mesh Product

21. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the GYNECARE TVT (the "TVT"), the product at issue in this case, sometimes referred to herein as the "Pelvic Mesh Product."

22. Defendants' Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakening or damage to the walls of the vagina. The Pelvic Mesh Products are represented by Defendants to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks or to prevent stress urinary incontinence by implantation of a strip of mesh under the urethra for support. The Pelvic Mesh Products were and are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting stress urinary incontinence and pelvic organ prolapse.

23. Prior the implantation of the Pelvic Mesh Product at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the

Pelvic Mesh Product under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

24. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Products, including the TVT, is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

1. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).
2. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).

3. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).
4. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
5. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
6. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).
7. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy

which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).

8. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).

9. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

10. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor

restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol, 2004. 171(5): p. 1970-3.

11. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. Curr Opin Obstet Gynecol. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

25. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Product is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

26. The Pelvic Mesh Product has been and continues to be marketed to the medical community and to patients as a safe, effective, and reliable medical device that can be implanted by safe, effective, and minimally invasive surgical techniques.

27. Defendants marketed and sold the Pelvic Mesh Products, including the TVT, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient

brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

28. Contrary to the representations and marketing of Defendants, the Pelvic Mesh Products, including the TVT, have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Product and the immune reaction that results;

b. the design of the Pelvic Mesh Product to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade;

e. degradation of the mesh itself over time which causes the internal tissue to degrade;

f. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

g. the design of the trocars (devices used to insert the Pelvic Mesh Product into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

29. Pelvic mesh products used for the surgical management of stress urinary incontinence (SUI) in women are primarily two different designs: the transobturator sling (frequently referred to as a TOT or TVT-O) and the retropubic sling (frequently referred to as a TVT and the type of product at issue in this case). The transobturator sling passes through the obturator space into the thigh, while the retropubic sling hammocks the urethra and exits up and out behind the pubic bone. In 2006, Defendants also began selling a "mini-sling," named the TVT-Secur, which was a shorter sling anchored directly to either the retropubic fascia (the "U method") or the obturator internus muscle (the "H method").

30. Retropubic slings cause nerve injuries, including pudendal neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome Type 2. These diagnoses are known for their disabling vaginal pain what makes sexual intercourse impossible, pelvic pain that reduces mobility to a sedentary level, and bowel and bladder dysfunction that may include an inability to evacuate the bowels and bladder associated with severe anorectal pain.

31. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of their Pelvic Mesh Products, including the TVT and its predicate devices, to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

32. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices.

33. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that

had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants are some of the manufacturers of the products that are the subject of the notification.

34. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **"continuing serious concern"** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh

may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 201l, was known or knowable to Defendants and was not disclosed in any manner.

35. Defendants have further known the following:

a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Product was and is causing numerous patients severe injuries and complications.

36. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendants actively and intentionally misled and continue to mislead the public into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

37. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

38. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Product; thus, in the event of a failure, injury, or complications, it is

impossible to easily and safely remove the Pelvic Mesh Products.

39. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable alternative procedures and instruments for repair of stress urinary incontinence have existed at all times relevant to this matter, including, but not limited to the following: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF).

40. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

41. Defendants provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Product, and thus increase the sales of this product

42. The Pelvic Mesh Product implanted into Plaintiff Rachel Howe was in the same or substantially similar condition as it was when it left the possession of Defendants, as well as being in the condition directed by and expected by these Defendants

43. Plaintiff Lela King and her physician foreseeably used and implanted the Pelvic Mesh Product, and did not misuse or alter this product in an unforeseeable manner.

44. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Product include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain

during sexual intercourse), allodynia, blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

45. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Product) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the device.

46. Defendants knew and had reason to know that the Pelvic Mesh Product could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

47. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

48. The Pelvic Mesh Products were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

49. The TVT is designed to be inserted into and through the pelvic floor muscles, placing it in proximity to the pudendal nerve; Defendants failed to study or account for anatomic variations of the pudendal nerve when designing the device.

50. The Pelvic Mesh Products were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic pain, neuralgia, among other mesh-related issues.

Plaintiff's TVT Implantation

51. Upon information and belief, Robert J. Evans, M.D., recommended the Pelvic Mesh Product to Plaintiff LELA KING as appropriate and safe for the treatment of stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Product.

52. On June 30, 2003, Plaintiff LELA KING underwent surgery to address her stress urinary incontinence at Moses Cone Health System, 1200 North Elm Street, Greensboro, NC 27401. During this surgery, she was implanted with an Ethicon Gynecare TVT, Catalog No. 810041A, Lot Number JCG03087, by Dr. Robert J. Evans, M.D.

53. On May 9, 2014, Plaintiff LELA KING filed a complaint in the pelvic mesh MDL pending in the United States District Court for the Southern District of West Virginia (the "MDL") for injuries arising out of the implantation of her TVT product. On June 4, 2018, Plaintiff voluntarily dismissed her case pursuant to MDL PTO 293/298, which provided her the opportunity to refile her case within five years in the event she underwent a revision surgery for her mesh product or had the recommendation to undergo revision of her mesh product.

54. On October 21, 2019, Plaintiff was seen by Dr. Dionysios Veronikis, M.D. for evaluation of pain complaints related to her TVT sling, including significant vaginal pain, groin

pain, pelvic pain and dyspareunia. On October 22, 2019, at Mercy Hospital in St. Louis, Missouri, Plaintiff Lela King underwent surgery with Dr. Veronikis to excise the TVT sling.

55. As a direct and proximate cause of having the Gynecare TVT sling implanted in her, Plaintiff LELA KING has experienced significant mental and physical pain and suffering, to include dyspareunia, disabling pelvic pain, vaginal pain, pelvic pain, groin pain, neuromuscular pain, dysuria, urinary frequency, urinary urgency, stress incontinence, has sustained permanent injury and scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

56. Pursuant to MDL PTO 293/298, this case is being filed within two years of Plaintiff undergoing revision surgery of her TVT mesh product.

Defendants' Tortious Conduct

57. Defendants' TVT Pelvic Mesh Product was implanted in Plaintiff to treat her SUI, the use for which Defendants designed, manufactured, marketed, and/or sold this product.

58. At all times relevant to this matter, Defendants marketed their Pelvic Mesh Products (including the TVT Pelvic Mesh Product) to the medical community, medical device manufacturers, and patients and consumers as safe, effective, and reliable medical devices that could be implanted by safe, effective, and minimally invasive surgical techniques for the treatment of medical conditions, primarily POP and SUI, and as being safer and more effective as compared to other products and procedures for treatment of similar conditions.

59. Defendants marketed and sold their Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) to medical device manufacturers, the medical community at large, and patients through carefully planned, multifaceted marketing campaigns

and strategies. These campaigns and strategies included, without limitation, direct-to-consumer advertising including aggressive marketing to healthcare providers at medical conferences, hospitals, and private offices, and the provision of valuable consideration and benefits to healthcare providers. Defendants also utilized documents, brochures, websites, and/or telephone information lines in offering exaggerated and misleading expectations as to the safety and utility of the products.

60. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendants' Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) have high failure rates and high injury and complication rates, fail to perform as intended, require frequent and often debilitating operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff.

61. Defendants have consistently underreported and withheld information about the propensity of the Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) to fail and to cause injury and complications, have misrepresented the efficacy and safety of their Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) through various means and media, and have actively and intentionally misled the FDA, the medical community, patients, and the public at large about those products.

62. Defendants have known at all times and had reason to know that their Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) were and are causing numerous patients severe injuries and complications including those suffered by Plaintiff, and that their disclosures to the FDA were and are incomplete and misleading. Defendants suppressed this information and failed to accurately and completely disseminate or

share this information and other critical information with the FDA, healthcare providers, and patients. As a result, Defendants actively and intentionally misled and continue to mislead the public, including the medical community, healthcare providers, and patients, including Plaintiff and her doctor into believing that their Pelvic Mesh Products were and are safe and effective, which led to the prescribing and implantation of the TVT Pelvic Mesh Product into Plaintiff.

63. Defendants individually and/or jointly failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case).

64. Knowing the significant risk that the Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) would fail and/or imperil the health and welfare of the women in which they were implanted, Defendants failed to properly design the Pelvic Mesh Products or to establish a safe, effective procedure for the removal of the Pelvic Mesh Products, rendering it impossible to safely or easily remove the Pelvic Mesh Products leading to foreseeable injuries to patients, including Plaintiff.

65. Feasible and suitable alternative designs and products, as compared to Defendants' Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and other similar conditions, have existed at all relevant times, including, but not limited to the following examples: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic sling comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF), or a retropubic mini-sling, such as the TFS device from TFS

Surgical.

66. The Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) were at all times utilized and implanted in a manner foreseeable to Defendants including the implantation of Plaintiff's TVT Pelvic Mesh Product.

67. Defendants have provided incomplete, insufficient, and misleading training and information to physicians in order to increase the number of physicians utilizing the Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case), and thus increase the sales of the Pelvic Mesh Products. This has led to the dissemination of inadequate and misleading information to doctors and patients, including Plaintiff and her physicians.

68. The TVT Pelvic Mesh Product implanted into Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by Defendants.

69. The injuries, conditions, and complications, some or all of which were and/or will be reasonably expected to be suffered by Plaintiff and others due to the Pelvic Mesh Product include without limitation dyspareunia, vulvar, perineal, and/or perianal allodynia, spastic pelvic floor syndrome, Chronic Regional Pain Syndrome Type II, pudendal neuralgia, ilioinguinal neuralgia, pelvic pain, groin pain, vaginal pain, inner thigh pain, paresthesia, depression, and impaired bladder function, as well as other symptoms.

70. Despite knowledge of these catastrophic injuries, conditions, and complications caused by the Pelvic Mesh Products, Defendants manufactured, marketed, and sold the Pelvic Mesh Products while failing to adequately warn, label, instruct, and disseminate information with regard to the Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

71. On or about January 3, 2012, the FDA ordered Defendants to conduct randomized, controlled clinical testing of the Pelvic Mesh Products or be ordered to cease their manufacture, marketing, and sale.

72. On or about June 5, 2012, Product Liability Defendants announced that they were withdrawing some of their Pelvic Mesh Products from the market and, as a result, would not be conducting the randomized, controlled clinical testing ordered by the FDA.

73. As of the date of the filing of Plaintiff's Complaint, Product Liability Defendants have not begun or completed any of the randomized, controlled clinical testing ordered by the FDA.

74. The Gynecare TVT was designed to be permanently implanted into a woman's body yet the product changes after implantation: The TVT contracts over time which, *inter alia,* can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function, and can cause fibrosis of muscles, adhesions between tissues, an inflammation which impair sexual function, mobility, bowel and bladder function, and cause chronic pelvic pain.

75. The risk of serious injuries was known or should have been known to Defendants, but in spite of these risks, Defendants continued to market their pelvic mesh devices, including the TVT Pelvic Mesh Product, for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

76. Had Defendants properly and adequately disclosed the risks associated with the pelvic mesh product for transvaginal use, including the TVT Pelvic Mesh Product device at issue, Plaintiff would not have agreed to treatment with the device and on information and belief, Plaintiff's implanting physician would have advised her of the risks as part of his informed

consent, and/or otherwise altered his prescribing habits, such as recommending a different procedure or device or no surgical treatment.

77. The injuries suffered by Plaintiff were caused by the wrongful acts, and/or omissions, and representations of Defendants, as outlined above.

78. As a direct and proximate result of having the Gynecare TVT device implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include any of the following: dyspareunia, disabling pelvic pain, urinary frequency, urinary urgency, stress incontinence, vulvodynia, chronic bladder pain, has sustained permanent injury and scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT I: NEGLIGENCE – FAILURE TO WARN & DESIGN DEFECT

79. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

80. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case.

81. Defendants breached their duty to exercise reasonable care in the design and marketing of the TVT Pelvic Mesh Product, for the reasons articulated more fully below.

Failure to Warn

82. Defendants' TVT Pelvic Mesh Product breached their duty of care owed to

Plaintiff and/or her health care providers by failing to adequately warn or instruct Plaintiff and/or her health care providers.

83. Set forth below are the warnings, precautions, contraindications, and adverse reactions in the Instructions for Use (IFU) for the TVT device implanted in Plaintiff:

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- **Do not use TVT procedure for patients who are on anti-coagulation therapy.**
- **Do not use TVT procedure for patients who have a urinary tract infection.**
- Users should be familiar with surgical technique for bladder neck suspensions before employing the TVT device. It is however important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

84. In their IFU, as well as the marketing materials they prepared and disseminated to patients and healthcare providers, Defendants omitted critical information regarding the risks and potential complications of the TVT Pelvic Mesh Product at issue in this case. Specifically, Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the following (subsequently referred to as the "Risks and Potential Complications"):

a. That the TVT was not studied prior to launch for safety and efficacy;

b. That the TVT has propensities to contract, retract, and/or shrink inside the body;

c. That the TVT has propensities for degradation, fragmentation, and/or creep;

d. That the TVT's inelasticity prevents proper mating with the pelvic floor and vaginal region;

e. The magnitude of the risk of mesh erosion or extrusion;

f. The risk of chronic inflammation resulting from the TVT;

g. The risk of chronic infections resulting from the TVT;

h. The risk of developing chronic regional pain syndrome as a result of chronic inflammation/infection;

i. The risk of permanent vaginal or pelvic scarring as a result of the TVT;

j. The risk and/or magnitude of recurrent, intractable pelvic pain, nerve pain, and other pain resulting from the TVT;

k. The risk of direct nerve injury to the ilioinguinal nerve;

l. The risk of secondary nerve injury or irritation to the ilioinguinal nerve;

m. The risk of direct nerve injury to the pudendal nerve;

n. The risk of secondary nerve irritation to the pudendal nerve;

q. The magnitude of the risk of dyspareunia (painful sexual intercourse) in patients;

r. That the TVT may result in dyspareunia that makes vaginal penetration impossible;

s. The risk of vulvar, perineal, or perianal allodynia;

t. The frequency with which the need for corrective or revision surgery to adjust or remove the TVT may occur in patients;

u. The magnitude of the risk of acute and long-term complications that could arise as a result of implantation of the TVT in patients;

v. The hazards associated with the TVT, including pudendal and ilioinguinal neuralgia, permanent nerve damage, and pelvic floor and groin myalgia;

w. That treatment of SUI with the TVT exposes patients to greater risk than feasible available devices for SUI, including pelvic mesh products utilizing alternative

polypropylene material or non-polypropylene surgical products, alternatives, and procedures;

x. That treatment with the TVT makes future surgical repair more difficult than feasible available alternatives;

y. That TVT offers no improvement in efficacy compared to non-mesh repairs and non-mesh repairs do not place the obturator, ilioinguinal, or pudendal nerve at risk acutely or over time;

z. That use of the TVT puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

aa. That removal of the TVT due to complications may significantly impair the patient's quality of life;

bb. That complete removal of the TVT may not be possible;

cc. That complete removal of the TVT may not result in complete resolution of the complications, including pain;

dd. The foreseeable and unavoidable risk of acute pudendal, and/or ilioinguinal neuralgia or pudendal, and/or ilioinguinal neuralgia occurring months or years after implantation;

ee. The magnitude of the risk of pudendal and/or ilioinguinal neuralgia; and

ff. The risk of permanent injury and pain to the muscles and soft tissues of the pelvic floor that may occur acutely after implantation or become symptomatic months or years after implantation.

85. Arguing further, Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most

effective methods of, implantation and use of Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case. Defendants also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

86. The Pelvic Mesh Product at issue herein was expected to, and did, reach the intended consumers, handlers, and persons receiving the products, including Plaintiff, with no substantial change in the condition in which the products were designed, produced, manufactured, sold, distributed, labeled and marketed by Defendants.

87. Defendants further breached their duty of care by not providing sufficient or adequate warnings regarding, among other subjects:

a. The propensities of the Pelvic Mesh Product at issue herein to contract, retract, and/or shrink inside the body;

b. The propensities of the Pelvic Mesh Product at issue herein for degradation, fragmentation, disintegration and/or creep;

c. The inelasticity of the Pelvic Mesh Product at issue preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Product at issue herein;

f. The risk of chronic infections resulting from the Pelvic Mesh Product at issue herein;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Product at issue herein;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Product at issue herein;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Product at issue herein;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein, including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Product at issue herein;

l. The defects of the Pelvic Mesh Product at issue as described herein;

m. Treatment of stress urinary incontinence with the Gynecare TVT is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Gynecare TVT exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Gynecare TVT makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Product at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Pelvic Mesh Product at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life and intimate personal relationships;

r. Complete removal of the Pelvic Mesh Product at issue herein may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein.

88. Defendants, by exercising reasonable care, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

89. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Pelvic Mesh Product at issue herein, and Plaintiff was directly and proximately caused injury as a result.

90. By reason of the foregoing, Plaintiff has damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

91. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

Design Defect

92. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

93. Defendants further breached their duty of care owed to Plaintiff and/or her health care providers by failing to exercise reasonable care in the design of the TVT Pelvic Mesh Product.

94. The Pelvic Mesh Product at issue herein, the Gynecare TVT device, was designed, marketed, manufactured and distributed by Defendants and was defective and not reasonably safe due to its improper, inadequate, and defective design.

95. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein and Plaintiff was an expected user or consumer of the mesh product.

96. Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, were defectively and improperly designed, rendering the products deficient and unreasonably dangerous and hazardous to Plaintiff.

97. The TVT Pelvic Mesh Product at issue herein that was implanted in Plaintiff was conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the pelvic mesh product, like Plaintiff.

98. The TVT Pelvic Mesh Product at issue herein that was implanted in Plaintiff was, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, labeled and/or sold. There were also safer alternative designs for the device.

99. Defendants failed to exercise reasonable care in the design of the TVT Pelvic Mesh Product. The TVT Pelvic Mesh Product's design defects include, but are not limited to, the following:

a. The use of polypropylene in the TVT and the foreseeable adverse tissue reactions, host defense response, and immune reactions that result from such material leading to ongoing degradation of the mesh, shrinkage, perpetual scarification as the mesh degrades all of which have potential to

produce adverse reactions and permanent injuries including but not limited to painful recurrent erosions, direct muscle and soft tissue injury, nerve entrapment or irritation of adjacent nerves, and associated intractable neuropathic pain and myofascial pain;

b. The design of the TVT to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

c. The design of the TVT to be inserted into and through the pelvic floor muscles produces a foreseeable risk of acute and chronic myofascial pain;

d. The design of the TVT to be inserted into and through the pelvic floor muscles produces a foreseeable risk of pudendal neuralgia through its connection with the obturator internus that may present acutely or months to years after implantation;

e. The design of the TVT to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

f. Biomechanical issues with the design of the TVT, including, but not limited to, the propensity of the TVT mesh to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in serious and permanent injury to the soft tissues and muscles of the pelvic floor without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

g. The use and design of arms and anchors in the Pelvic Mesh Product at issue herein, which, when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

h. The propensity of the Pelvic Mesh Product at issue herein for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

i. The inelasticity of the TVT mesh, causing the products to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, or walking) without providing any additional therapeutic benefit when compared to other surgical treatment options for SUI:

j. The propensity of the TVT mesh to degradation or fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

k. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

l. The propensity of the product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

m. The hardening of the Pelvic Mesh Product at issue herein in the body;

n. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions that are unique to polypropylene without providing any additional therapeutic benefit when compared to other non-polypropylene surgical treatment options for SUI; and

o. The use of polypropylene material in the Pelvic Mesh Product at issue herein and the failure to provide adequate instructions for use ("IFU") and training.

100. As designed, Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, were and are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

101. Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products

102. Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, are not reasonably safe and so likely to be harmful to users that a reasonable person who had actual knowledge of their potential for producing injury would conclude that it should not have been marketed.

103. Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, are dangerous beyond that which would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community as to its characteristics.

104. Defendants have intentionally and recklessly designed, marketed, labeled, sold, and distributed their Pelvic Mesh Products (including the TVT Pelvic Mesh Product at issue in this case) with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of Plaintiff.

105. At all relevant times, safer, technically and economically feasible, mesh-related alternative designs to the TVT existed. First, there were designs containing no synthetic,

polymer-based sling material, such as the Burch Procedure colposuspension with delayed absorbable sutures, autologous fascia slings, and an allograft sling using a product like Repliform or other biological matrix; said slings would have been more biologically compatible with human tissue and would have therefore prevented the foreign body immune response that promotes degradation of the pelvic tissue and other complications. Second, there were slings constructed with less polypropylene such as Ultrapro, a retropubic mini-sling, such as the TFS device from TFS Surgical; said slings, by utilizing less polypropylene, would have ameliorated the foreign body immune response that promotes degradation of the pelvic tissue and other complications described herein. Finally, there were retropubic slings or retropubic mini-slings comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF), a material which has greater biostability and biocompatibility than polypropylene, preventing the level of foreign body immune response that promotes degradation of the pelvic tissue and other complications described herein.

106. With respect to Plaintiff in particular, flaws with the TVT design, including but not limited to the use of polypropylene mesh in the TVT, the weight and pore size of the polypropylene mesh used in the TVT device, and the retropubic design of the device[1], caused and created chronic inflammation and chronic foreign body reaction inside of Plaintiff, as well entrapment, aggravation, irritation and compression of Plaintiff's pudendal and/or ilioinguinal nerves, which in turn damaged and aggravated the surrounding soft tissues. As a direct and proximate result of these design flaws, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia, vulvodynia, nerve pain/irritation, pelvic pain,

[1] As stated previously, the retropubic design of the TVT requires it be inserted into and through: (1) the muscles of the pelvic floor, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of pudendal neuralgia through its connection with the obturator internus muscle; and (2) the rectus abdominal muscles, producing a foreseeable risk of ilioinguinal neuralgia.

depression, and recurrent prolapse/incontinence, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, subsequent surgical removal of the mesh, loss of enjoyment of life, and economic damages. Plaintiff did not suffer from said injuries prior to implantation of the TVT Pelvic Mesh Product, and upon information and belief would not have suffered these injuries absent implantation of the TVT Pelvic Mesh Product. Plaintiff believed the TVT Pelvic Mesh Product would address her stress urinary incontinence, and did not know—nor did she have any reason to know, based upon the information provided to her and provided to her implanting physician regarding the risks of the TVT Pelvic Mesh Product, that she would sustain the injuries from the TVT Pelvic Mesh Product described herein.

107. As a direct and proximate result of Defendants' breach of the standard of care in the design of the TVT Pelvic Mesh Product, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

108. By reason of the foregoing, Plaintiff has damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

109. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II: FRAUD

110. Plaintiff repeats and re-alleges the paragraphs above as if specifically set forth herein and additionally or in the alternative, if same be necessary, further alleges as follows:

111. Ethicon Defendants falsely and fraudulently represented to Plaintiff, her physicians, and to members of the general public that the Pelvic Mesh Product was safe,

effective, reliable, consistent, and better than the other similar pelvic repair procedures when used in the manner intended by the manufacturer. Ethicon Defendants' false and fraudulent representations include but are not limited to:

a. Underreporting and withholding information from the FDA, physicians, and to members of the general public about the propensity of their Pelvic Mesh Products, including the TVT and its predicate devices, to fail and cause injury and complications;

b. Representing to physicians and to members of the general public that their Pelvic Mesh Products, including the TVT product at issue in this case, were safe and effective while withholding information that its Products were causing numerous patients severe injuries and complications;

c. Providing information to physicians regarding their Pelvic Mesh Products, including the TVT product at issue, that was incomplete, misleading, and insufficient with respect to the risks, hazards, and complication rates of the Products in an effort to increase Product usage and sales;

d. Representing that the risks of their Pelvic Mesh Products, including the TVT product at issue, were minimal and transient despite knowledge that said Products could cause serious and permanent injuries; and

e. Representing and marketing to physicians and to members of the general public that the polypropylene mesh in the Pelvic Mesh Products is safe, biologically compatible, and inert, despite knowledge that said mesh is biologically incompatible, promotes an inflammatory immune response, and is at risk of contraction, shrinkage, and degradation.

112. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

113. In representations to Plaintiff and/or to Plaintiffs healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That Defendants' Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the risk of adverse events with Defendants' Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That Defendants' Pelvic Mesh Products were not adequately tested;

d. That the limited clinical testing revealed Defendants' Pelvic Mesh Products had a higher risk of adverse effects in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e. That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f. That Defendants deliberately chose to forego studies that might reveal the true rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to Plaintiff, the medical community, or the regulatory authorities;

g. That Defendants were aware of dangers in Defendants' Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

h. That Defendants' Pelvic Mesh Products were defective and that they caused dangerous and adverse effects, including but not limited to higher incidence of erosion and failure at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

i. That patients needed to be monitored more regularly than usual while using Defendants' Pelvic Mesh Products and that, in the event the products needed to be removed, the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

j. That Defendants' Pelvic Mesh Products were designed negligently; and

k. That Defendants' Pelvic Mesh Products were designed defectively.

114. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of Defendants' Pelvic Mesh Products, including but not limited to the heightened risks of erosion, failure, and permanent injury.

115. Defendants had sole access to material facts concerning the defective nature of the products, their propensity to cause serious and dangerous side effects, and hence to cause dangerous injuries and damage to persons who used Defendants' Pelvic Mesh Products.

116. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made purposefully, willfully, wantonly, and/or recklessly to mislead and to cause Plaintiffs physicians and healthcare providers to purchase, prescribe, and/or

dispense the Pelvic Mesh Products, and/or to mislead Plaintiff into reliance and to cause Plaintiff to use Defendants' Pelvic Mesh Products.

117. At the time these representations were made by Defendants, and at the time Plaintiff used the Pelvic Mesh Products, Plaintiff was unaware of the falsehood of these representations and reasonably believed them to be true.

118. Defendants knew and had reason to know that Defendants' Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Products and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

119. In reliance upon these false representations, Plaintiff was induced to and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions and that these included material omissions of facts surrounding the use of Defendants' Pelvic Mesh Products, as described in detail herein.

120. Plaintiff and her physicians reasonably relied on information propagated ' by Defendants which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of Defendants' Pelvic Mesh Products.

121. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including without limitation assuring Plaintiff, the public, and Plaintiffs healthcare providers and physicians that Defendants' Pelvic Mesh Products were safe and effective for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or

procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

122. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, Plaintiffs healthcare providers, and the FDA.

123. The information distributed by Defendants to the public, the medical community, the FDA, and Plaintiff included without limitation websites, product brochures and pamphlets, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations. This information was false and misleading and contained omissions and concealment of the truth about the dangers of the use of Defendants' Pelvic Mesh Products.

124. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of Defendants' Pelvic Mesh Products, specifically that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns and that Defendants' Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

125. Defendants intentionally failed to inform the public, including Plaintiff, of the severity and frequency of complications from the Pelvic Mesh Devices, the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

126. Defendants chose to over-promote the purported safety, efficacy, and benefits of Defendants' Pelvic Mesh Products instead.

127. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and to induce Plaintiff, the public, and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use Defendants' Pelvic Mesh Products.

128. Defendants made claims and representations in their documents submitted to the FDA and their reports to the public and to healthcare professionals and in advertisements that Defendants' Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

129. These representations, and others made by Defendants, were false when made, were made with the pretense of actual knowledge when such knowledge did not actually exist, and/or were made recklessly and without regard to the true facts.

130. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding Plaintiff and Plaintiffs healthcare professionals; were made in order to induce Plaintiff and her healthcare professionals to rely on misrepresentations; caused Plaintiff to purchase, rely on, use, and request Defendants' Pelvic Mesh Products; caused her healthcare professionals to dispense, recommend, or prescribe Defendants' Pelvic Mesh Products.

131. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of Defendants' Pelvic Mesh Products to the

public at large for the purpose of influencing the sales of products known to be dangerous and defective and/or not as safe as other alternatives.

132. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false representations for the purpose of deceiving and lulling Plaintiff, as well as her healthcare professionals, into a false sense of security so that Plaintiff and her healthcare providers would rely on Defendants' representations, that Plaintiff would request and purchase Defendants' Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe, and recommend Defendants' Pelvic Mesh Products.

133. Defendants utilized direct-to-consumer advertising, including product brochures and pamphlets, to market, promote, and advertise Defendants' Pelvic Mesh Products.

134. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the ,use of Defendants' Pelvic Mesh Products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor could Plaintiff have discovered with reasonable diligence the true facts or Defendants' misrepresentations.

135. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Defendants' Pelvic Mesh Products, Plaintiff would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

136. Defendants' wrongful conduct constitutes fraud and deceit and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

137. The true facts include, but are not limited to, that the Pelvic Mesh Product was not safe to be used for treatment of urinary incontinence, and was, in fact, dangerous to the health and body of Plaintiff.

138. When Ethicon Defendants made these representations, it knew that they were false. Ethicon Defendants made said representations with the intent to defraud and deceive Plaintiff and/or her physicians, and with the intent to induce Plaintiff and/or her Physicians to act in the manner herein alleged, that is, to use the aforementioned product for treatment of urinary incontinence.

139. At the time Ethicon Defendants made the aforesaid representations, Plaintiff and/or her physicians took the actions herein alleged; Plaintiff and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiff was and/or her physician was induced to, and did, use the aforesaid Pelvic Mesh Product as herein described. If Plaintiff and/or her physician(s) had known the facts regarding the safety of the Pelvic Mesh Product, neither would not have taken such action. The reliance of Plaintiff and her physicians upon Ethicon Defendants' representations were justified because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

140. As a result of Ethicon Defendants' fraud and deceit, Plaintiff was caused to sustain the herein described injuries and damages.

141. In doing the acts herein alleged, Ethicon Defendants acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Ethicon Defendants and others from engaging in similar conduct in the future. Said wrongful conduct was done with

advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Ethicon Defendants.

142. As a direct and proximate result of Ethicon Defendants' fraud, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

143. By reason of the foregoing, Plaintiff has suffered damages for which she now seeks compensation.

144. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III: FRADULENT CONCEALMENT

145. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein; specifically, paragraphs 111-141 pertaining to Fraud.

146. Throughout the relevant time period, Defendants knew that their Pelvic Mesh Product was defective and unreasonably unsafe for their intended purpose. Specifically and by way of example, Defendants knew and concealed from physicians and the general public:

a. The propensity of their Pelvic Mesh Products, including the TVT and its predicate devices, to fail and cause injury and complications;

b. The severity and extent of injuries and complications being caused by their Pelvic Mesh Products, including the TVT and its predicate devices; and

c. That the polypropylene mesh used in its the Pelvic Mesh Products is biologically incompatible with vaginal tissues, promotes an inflammatory immune response, and is at risk of contraction, shrinkage, and degradation, among other complications.

147. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, her physicians, and the medical community that their Pelvic Mesh Product was defective, unsafe, unfit for the purposes intended, and not of merchantable quality.

148. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Pelvic Mesh Product because:

a. Defendants were in a superior position to know the true quality, safety, and efficacy of Defendants' Pelvic Mesh Product;

b. Defendants knowingly made false claims about the safety and quality of Defendants' Pelvic Mesh Product in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of Defendants' Pelvic Mesh Product from Plaintiff.

149. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use Defendants' Pelvic Mesh Product.

150. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Pelvic Mesh Product so that Plaintiff would request and purchase Defendants' Pelvic Mesh Product and so that her healthcare providers would dispense, prescribe, and

recommend Defendants' Pelvic Mesh Product, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of Defendants' Pelvic Mesh Product.

151. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of Defendants' Pelvic Mesh Product, and are subject to the same liability to Plaintiff for her pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Pelvic Mesh Product's lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth. Defendants are therefore liable for fraudulent concealment under all applicable law, including, inter alia, Restatement of Torts§ 402A.

152. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, impairment of sexual function, impairment of bladder function, loss of enjoyment of life, and economic damages.

153. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV: VIOLATION OF NORTH CAROLINA CONSUMER PROTECTION ACT

154. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein; specifically, paragraphs 111-141 pertaining to Fraud.

155. Plaintiff purchased and used Defendants' Pelvic Mesh Product primarily ·for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

156. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Defendants' Pelvic Mesh Product and would not have incurred related medical costs and injury.

157. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

158. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

159. Specifically, and by way of example, Defendants:

a. represented to physicians and to members of the general public that their Pelvic Mesh Products, including the TVT product at issue in this case, were safe and effective while withholding information that its Products were causing numerous patients severe injuries and complications;

b. provided information to physicians regarding their Pelvic Mesh Products, including the TVT product at issue, with respect to the risks, hazards, and complication rates of the Products that was incomplete, misleading, and insufficient, in an effort to increase Product usage and sales;

c. represented that the risks of their Pelvic Mesh Products, including the TVT product at issue, were minimal and transient despite knowledge that said Products could cause serious and permanent injuries; and

d. represented and marketed to physicians and to members of the general public that the polypropylene mesh in the Pelvic Mesh Products is safe, biologically compatible, and inert, despite knowledge that said mesh is biologically incompatible, promotes an inflammatory immune response, and is at risk of contraction, shrinkage, and degradation.

160. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell Defendants' Pelvic Mesh Product. Each aspect of Defendants' conduct combined to artificially create sales of Defendants' Pelvic Mesh Product.

161. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Defendants' Pelvic Mesh Product.

162. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Product, would not have consented to their implantation, and would not have incurred related medical costs.

163. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

164. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

165. Defendants have engaged in unconscionable commercial practices; deception; fraud; false pretense; false promise; misrepresentation; knowingly concealed, suppressed and omitted material facts with the intent that others rely on such concealment, suppression or omission, with subsequent performance. All of these acts were undertaken in connection with the sale and advertisement of the Pelvic Mesh Product, in violation of New Jersey Statute § 56:7-2 (entitled "Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice").

166. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants were the supplier, manufacturer, advertiser, and seller subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

167. Defendants violated the statute that was enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising by knowingly and falsely representing that Defendants' Pelvic Mesh Product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

168. The acts and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

169. Defendants had actual knowledge of the defective and dangerous condition of Defendants' Pelvic Mesh Product and failed to take any action to cure such defective and dangerous conditions.

170. Plaintiff's healthcare providers and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

171. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, constituted unfair and deceptive acts and practices.

172. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

173. As a direct and proximate result of Defendants' violations of the state's consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

174. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V: GROSS NEGLIGENCE

175. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein; specifically, paragraphs 111-141 pertaining to Fraud.

176. Defendants, by and through their officers, directors, and/or managers, sold and/or condoned to be sold their Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, to Plaintiff's healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area.

177. Defendants, by and through their officers, directors, and/or managers, sold and/or condoned to be sold their Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, to Plaintiff's healthcare providers and other healthcare providers throughout the United States in spite of their knowledge that their Pelvic Mesh Products can shrink, disintegrate, degrade inside the body, and/or cause the other problems heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by Plaintiff.

178. At all relevant times, Defendants, including Defendants' officers, directors, or managers, knew or should have known that their Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, were inherently dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, and remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

179. At all relevant times, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh

Product at issue in this case, with said conduct being participated in or condoned by Defendants' officers, directors, and/or managers.

180. Defendants' misrepresentations, made and/or condoned by Defendants' officers, directors, and/or managers, knowingly withheld material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case.

181. At all relevant times, Defendants, including Defendants' officers, directors, and/or managers, knew and willfully and wantonly disregarded the fact that Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

182. At all relevant times, Defendant, including Defendants' officers, directors, and/or managers, knew and willfully and wantonly disregarded the fact that Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise healthcare providers and the public of the same.

183. At all relevant times, Defendants, including Defendants' officers, directors, and/or managers, willfully and wantonly misstated and misrepresented data and continue to willfully and wantonly misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case.

184. Notwithstanding the foregoing, Defendants, including Defendants' officers, directors, and/or managers, continue to willfully and wantonly market Defendants' Pelvic Mesh Products to consumers without disclosing the true risk of side effects and complications, including the TVT Pelvic Mesh Product at issue in this case.

185. Defendants, including Defendants' officers, directors, and/or managers, knew of their Pelvic Mesh Products' defective and unreasonably dangerous nature, but willfully and wantonly continued to manufacture, produce, assemble, market, distribute, and sell Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Defendants' Pelvic Mesh Products.

186. Defendants, including Defendants' officers, directors, and/or managers, continue to willfully and wantonly conceal and/or fail to disclose to the public, including Plaintiff, the serious side effects of Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, in order to ensure continued and increased sales.

187. Defendants' willful and wanton failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using Defendants' Pelvic Mesh Products, including the TVT Pelvic Mesh Product at issue in this case, against their benefits.

188. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services and has incurred medical, healthcare, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

189. Plaintiff alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

PUNITIVE DAMAGES

190. Plaintiff is further entitled under New Jersey law to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, gross negligence, wanton and reckless conduct, and their complete and total reckless disregard for the public safety and welfare.

191. Defendants had knowledge of or should have had knowledge of, and/or were in possession of evidence demonstrating that the Pelvic Mesh Product at issue was defective and unreasonably dangerous and/or was an inappropriate choice for treatment of Plaintiff's SUI. Despite this knowledge, Defendants failed to, among other purposeful acts, inform or warn of the dangers, establish and maintain an adequate quality and post-market or post-implant surveillance system, and/or recall the Pelvic Mesh Product.

192. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, Plaintiff has suffered and will continue to suffer serious physical and mental injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

DEMAND FOR JURY TRIAL

193. Plaintiff hereby demands trial by jury as to all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against each of the Defendants, individually and jointly and severally, for compensatory damages and punitive damages and requests a trial by jury on all issues so triable as a matter of right and the following relief:

1. Compensatory damages for past, present, and future injuries, including without limitation:
    a. Past and future pain and suffering for the severe and permanent personal injuries sustained by Plaintiff;
    b. Past and future health and medical care costs;
    c. Past and future loss of earnings/diminished earning capacity;
    d. Past and future damages for mental anguish and emotional distress;
    e. Past and future damages for physical impairment; and
    f. Past and future damages for physical disfigurement;
2. Punitive or exemplary damages;
3. Reasonable attorneys' fees, as allowed by law;
4. Costs of suit;
5. Interest; and
6. Such other and relief as this Court deems just and proper.

Dated: July 29, 2022

Respectfully submitted,

FELDMAN AND PINTO

/s/ Laura Feldman

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I certify that on July 29, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF System, which will send notification of such filing to the CM/ECF participants registered to receive service in this cause.

Laura Feldman
LAURA FELDMAN